

REMARKS

Claims 1-51 are all the claims pending in the application.

Claims 1-51 are rejected under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. In summary, the Examiner asserts that Applicants are not seen to be in possession of the entire genus of compounds which are SGLT1 inhibitors and also show substantially no inhibitory effect on GLUT2 and/or GLUT5.

Applicants traverse.

In the present specification, it is described that SGLT1 inhibitory effects can be determined, for example, by the method described in Example 3, and GLUT 2 and GLUT5 inhibitory effects can be determined, for example, by the methods described in References 33 and 34. Particularly, please see "Fructose transport in membrane vesicles", right column on p. 193 of Reference 33, and "Experimental procedures", on p. 17765, and the footnotes of Fig. 1 on p. 17766 of Reference 34.

Therefore, one of ordinary skill in the art would find compounds useful for the present invention by evaluating GLUT2 and GLUT5 inhibitory effects on any known SGLT1 inhibitors such as the compounds described in WO 02/098892 or the like.

The present description discloses the compounds of Examples 1 and 2 having different structures, pharmaceutically acceptable salts thereof and hydrates thereof as selective SGLT1 inhibitors of the present invention (see p. 11, lines 14-17, and Examples 1 and 2), methods for preparing pharmaceutical compositions comprising the same (p. 15, lines 7-16), dosages of the active ingredients (p. 15, line 17 to p. 16, line 1), and that the compounds have SGLT1 inhibitory effect (Example 3) and substantially no inhibitory effect on absorbing fructose through the small intestine, that is, substantially no GLUT2 and GLUT 2 inhibitory effects (Test Example 1). The

present description also discloses that selective SGLT1 inhibitors, the compounds of Examples 1 and 2, exert extremely excellent hypoglycemic effect (Test Example 2 and Fig. 1).

Even though there might be only two compounds as a selective SGLT1 inhibitor in the present description, the present description describes the features of the claims as mentioned below.

First, at the time of filing, it was known that phlorizin is an SGLT inhibitor, and decreases blood glucose level by enhancement of urinary glucose excretion (p. 3, lines 11-14), and a metabolite of phlorizin, phloretin, inhibits GLUT (p. 5, lines 3-7). It was also known that GLUT2 and GLUT5 are localized at the small intestinal epithelial cells and involved in fructose absorption (p. 5, lines 9-14).

Second, the present inventors studied earnestly and found a certain compound which inhibits glucose and galactose absorptions by inhibiting SGLT1 which has substantially no effect on fructose absorption in the small intestine, while phlorizin, a known SGLT inhibitor, significantly inhibits fructose absorption (p. 12, lines 8-15). It was also found that such a compound exerts significant suppressive effect on hyperglycemia by various experiments, and thereby, the present invention has been completed.

Next, the present inventors investigated hypoglycemic effects caused by fructose ingestion by using acarbose and miglitol as α -glucosidase inhibitors, phlorizin as an SGLT inhibitor, and the compounds of Examples 1 and 2. As a result, it was confirmed that the selective SGLT1 inhibitor of the present invention exerts significant hypoglycemic effect by fructose ingestion. The result of phlorizin shows that fructose absorption was inhibited via GLUT inhibition by phloretin, and the results of the α -glucosidase inhibitors show that fructose absorption was inhibited by inhibiting of sucrose digestion into fructose and glucose. Both

results demonstrate hypoglycemic effect by fructose ingestion was inhibited by inhibition of fructose absorption (p. 12, line 16 to p. 13, line 17, Test Example 2 and Fig. 1).

As mentioned above, the present description discloses that SGLT inhibitors substantially showing no GLUT2 and/or GLUT5 inhibitory effect exert the excellent effects of the present invention with support by the various data obtained from the original experiments by the present inventors. Nothing is left to the imagination.

Accordingly, one of ordinary skill in the relevant art would recognize that Applicants were in possession of the claimed invention as of the effective filing date of the present application based upon the disclosure in the specification and the common technical knowledge available in the art (i.e., the state of the art) at the time that the present invention was made.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

RESPONSE UNDER 37 C.F.R. § 1.111
Application No.: 10/537,495

Attorney Docket No.: Q88234

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

/Jennifer M. Hayes/
Jennifer M. Hayes
Registration No. 40,641

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: April 28, 2010